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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/499,423 07/07/95 CAMPBELL

EXAMINER

F3M1/0317

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PAPER NUMBER

3308
DATE MAILED:

03/17/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

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OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/2/97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-117 is/are pending in the application.
Of the above, claim(s) 36-41 & 98-117 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-35 & 42-97 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-5, 24-30, 33-35, 42-49, 51-55, 57-61, 63-67 and 69-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee, 5,123,917. The expansion limit of the graft layer is reached due to the limit of expansion of the stent. The stent will permit only a predetermined expansion due to the stent configuration and structure. Additional application of internal pressure will not expand the stent or graft layer/tube. The device does not appear to have a recoil so the “or less” limitation is met by the zero (0) recoil of the tube.
3. Claims 1,2,5,24-30,33-35,42-48,51-54,58-60,63-66,69,70,72,74,76,78,80,82,84 and 86-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes, 5,122,154. The expansion limit of the graft layer is reached due to the limit of expansion of the stent. The stent will permit only a predetermined expansion due to the stent configuration and structure. Additional application of internal pressure will not expand the stent or graft layer/tube. The device does not appear to have a recoil so the “or less” limitation is met by the zero (0) recoil of the tube.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 6-16, 18, 19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee ('917) in view of Eilentropp, 4,791,966. Lee teaches all aspects of the claimed invention except for the helical wrapped PTFE layer. The Lee outer layer is a porous PTFE tube applied over the inner tubular layer and stent. Eilentropp teaches a PTFE tube formed by a helical layer of wrapped PTFE material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the outer layer of Lee of helically wrapped PTFE as taught by Eilentropp, because the helical layered tube would have been merely an alternate and analogous method of forming a tube on the Lee device.

6. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee ('917) in view of Eilentropp ('966) as applied to claim 14 above, and further in view of Summers ('445). The difference between the modified Lee device and the claimed invention is the use of a branched stent/graft with three ends. Summers teaches the use of a stent which can have a straight or branched configuration depending on the vessel that is to be supported. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the modified Lee stent/graft with a branched, three end configuration, because the branched configuration would have enabled the stent/graft to support and repair a branched vessel as taught by Summers. It should be noted that the branched, three end configuration would inherently form a larger and smaller end on the stent graft (i.e., tapered tube between first and second ends).

7. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee ('917) in view of Summers, 5,607,445. The difference between Lee and the claimed invention is

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the use of a branched stent/graft with three ends. Summers teaches the use of a stent which can have a straight or branched configuration depending on the vessel that is to be supported. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the Lee stent/graft with a branched, three end configuration, because the branched configuration would have enabled the stent/graft to support and repair a branched vessel as taught by Summers. It should be noted that the branched, three end configuration would inherently form a larger and smaller end on the stent graft (i.e., tapered tube between first and second ends).

8. Claims 20, 50, 56, 62 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee alone or Lee in view of Eilentropp. The difference between Lee and the claimed invention is the use of sutures to secure the stent/graft. The Examiner takes Notice that sutures would have been well known in the art at the time of the invention to secure a graft or stent/graft to a vessel to prevent migration of the device within the vessel. Therefore, it would have been obvious to one of ordinary skill in the art to have used sutures for enhanced securement of the Lee stent/graft to the vessel.

Response to Arguments

9. Applicant's arguments filed Dec. 02, 1997 have been fully considered but they are not persuasive. Lee, as stated in column 4, line 54, teaches the use of porous polymeric tube. Regarding the additional use of a stent in Lee or Rhodes, it should be noted that for prior art to anticipated a claim all the elements of the claimed invention must be present in the prior art. The

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fact that the prior art contains additional elements does not preclude the prior art from anticipating the claimed invention.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication should be directed to Michael Milano at telephone number (703) 308-2496.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 3300 Receptionist whose telephone number is (703) 308-0858.

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Milano.mm

March 13, 1998



Michael J. Milano
Primary Examiner
Group 3300, AU 3308